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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,212	08/21/2006	Yehoshua Aloni	SER-112	5571

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,212	ALONI ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/21/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of 1) arginine as the species of amino acids, 2) putrescine as the species of vitamins, 3) $ZnCl_2$ as the species of salts, and 4) arachidonic acid as the species of fatty acids in the communication filed on 12/12/2006 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 22-39 are pending and under examination.

Information disclosure statement

The information disclosure statement filed 08/21/2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. (See IDS document JP 02 049579.) It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claim 22 is objected to because of the following informalities:

Claim 22 uses acronyms without first defining what they represent in the independent claims (see for example, "IL-18BP"). While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Novick et al. (WO 99/09063; published 02/25/1999; filed 08/13/1998) in view Shibuya et al. (US Patent 6,406,909; issued June 18, 2002, filed July 10, 1998) and Ciccarone et al. (WO 02/077202; Published 10/03/2002; cited in the IDS filed 08/12/2006 as reference F1).

Novick et al. teach that the isolated IL-18BP is included in pharmaceutical compositions consisting of acceptable vehicles (page 4, lines 11 and 12). In addition, Novick et al. teach the production of recombinant IL-18BP with COS cells transfected with an IL-18BP plasmid DNA (page 39, lines 27-28). The IL-18BP proteins produced by the cells are secreted into the medium. After the COS cells are incubated for a period of 3 to 5 days in serum free DMEM, the

culture medium is collected for the isolation of IL-18BP (page 40, lines 2-4). Finally, Novick et al. teach that IL-18BP is preferentially expressed from CHO cells (page 33, line 13). However, Novick et al. do not teach any components of the serum free medium.

Shibuya et al. teach components of a serum free medium in Table 3, columns 14-15. The medium comprises asparagine at 32.5 mg/L, natrium chloride or (also called sodium chloride) at 1025 mg/L, sodium selenite at 0.0043 mg/L, insulin at 5 mg/ml, and wheat protein hydrolysate at 1 g/L (column 14, lines 29-30).

Shibuya et al. teach the medium further comprises glucose at a concentration of 8,000 mg/L. In addition, the medium further comprises alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, tryptophan, tyrosine, threonine, valine and glutamine.

The medium of Shibuya et al. comprises the vitamins including biotin, pantothenate, choline choride, folic acid, i-inositol, niaciamide, pyridoxine, riboflavin, Vitamin B12, thiamine, and putrescine. In addition, Shibuya et al. teach that the medium further comprises $CaCl_2$, KCl, $MgCl_2$, sodium phosphate, $CuCl_2$, and sodium bicarbonate as buffer. Moreover, Shibuya et al. teach that the medium further comprises soybean protein hydrolysate (column 14, lines 40). Finally, Shibuya et al. teach that the medium further comprises pyruvic acid (sodium pyruvate), and the protective agent Pluronic F-68.

Ciccarone et al. (WO 02/077202; Published 10/03/2002; cited in the IDS filed 08/12/2006 as reference F1) teach a serum free medium further comprises $ZnCl_2$ (page 43, table 1). Moreover, Ciccarone et al. (WO 02/077202; Published 10/03/2002; cited in the IDS filed 08/12/2006 as reference F1) teach that the medium further comprises alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, tryptophan, tyrosine, threonine, valine but not glutamine (page

43, table 1). Finally, Cicarrone et al. teach that the medium comprises the fatty acid linoleic acid (page 43, table 1), cyclodextrin (page 29, line 23), soy supplement or hydrolysate (page 42, line 15), and the hormone hydrocortisone (page 8, line 30).

Thus, it would be obvious for one skilled in the art to modify the method of producing IL-18BP as taught by Novick et al. (WO 99/09063; published 02/25/1999; filed 08/13/1998) by utilizing the components of the serum free medium as taught by Shibuya et al. (US Patent 6,406,909; issued June 18, 2002, filed July 10, 1998) and the components of the serum free medium as taught by Ciccarone et al. (WO 02/077202; Published 10/03/2002; cited in the IDS filed 08/12/2006 as reference F1) through routine optimization. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

One of ordinary skill in the art at the time the invention was made would been motivated at the time the invention was made to modify the method of producing IL-18BP as taught by Novick et al. by utilizing the serum free medium formulation of Shibuya et al. and Cicarrone et al. The person of ordinary skill in the art would have been motivated to make that modification because improved levels of recombinant protein expression are obtained from cells grown in serum-free medium (Cicarrone et al. page 7, lines 5-8) and serum free-medium has been developed in order to eliminate contaminants in serum such as viruses or pathogenic prions which must not remain in final products (Shibuya et al. column 1, lines 28-32). One skilled in the art would have expected success because methods of producing protein in serum free medium were available and practiced at the time the invention was made. Accordingly, the invention taken as a whole is prima facie obvious.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Art Unit 1647
Patent Examiner
January 18, 2007

/Bridget E Bunner/
Primary Examiner, Art Unit 1647